Section 9-SMDA Requirements and indications for use statement

510(k) Summary

Galil Medical - SeedNet™ System
510(k) Number

OCT 31 2000

K003065

Company Name:

Galil Medical Ltd.

Contact Person:

Dr. Roni Zvuloni,
IP & Regulatory Manager
Telephone: +972-4-959 10 80
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Trade Proprietary Name:

SeedNet™.

Classification Name:

CRYOSURGICAL UNIT

Classification:

GEH

Predicate Devices:

1. CRYO-HIT™ (K993695, K991517, K991272, K98013)
2. Endocare Cryocare Cryosurgical System Urethral Warming System (K963970)
3. Bracystepper Needle Template Guide, Template Grid (reusable) Btachygrid™ (single use pre-sterilized) (K972672) .

Indication for Use:

The SeedNet™ System, is intended for cryogenic destruction of tissue during surgical procedures.
The SeedNet™ System is specifically indicated for Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH").

Device Description:

The Galil Medical's SeedNet™ System is essentially the same device as Galil Medical LTD's cleared CRYO-HIT™ System (K993965) except for the following modifications:

1. CRYO-HIT™ is intended to be marketed under new Trade Mark Name: "SeedNet™".
2. Several computer screens have been combined and modified.
3. a Trans Urethral Warmer is made available.
4. a Probes Insertion Template is made available.
5. "Stick" mode is performed via the use of 20% of the freeze temperature to stick the probes.

The SeedNet™ has the same intended use as the Cryo-Hit™ and the SeedNet™ 's indication is one of the Cryo-Hit™'s indications. In addition. the SeedNet has the same technological characteristics as the Cryo-Hit™ except for the minor modifications described above. The SeedNet™ computer Screen and Stick modifications do not raise any new questions of safety or effectiveness because the functions of the device remain the same although the means of achieving them has changed. The SeedNet™'s Transurethral Warmer consists of the same components as the Endocare TUW . The SeedNet™ Template is virtually identical to the brachytherapy template. Therefore, these accessories do not raise any new safety or effectiveness questions. Thus the SeedNet™ is substantially equivalent to these predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Galil Medical LTD
c/o Mr. Jonathan S. Kahan
Hogan & Hartson
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K003065
Trade Name: SeedNet™ System
Regulatory Class: II
Product Code: GEH
Dated: September 28, 2000
Received: October 2, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K003065

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number

Prescription Use ✓ (Per 21 CFR 801.109) OR Over the Counter Use_____

for Mark N Milken
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003065